UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
	Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

TPP TRIAL DEFENDANTS' REPLY IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS OF DR. RENA CONTI

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

RULE

PRELIMINARY STATEMENT

Despite spending more than 40 pages defending Dr. Conti's speculative damages analysis, plaintiffs—like Dr. Conti—still cannot cite a single piece of economic literature supporting Dr. Conti's assumption that an adulterated but clinically efficacious drug provides zero value. Plaintiffs also fail to establish that Dr. Conti is capable of calculating damages for the subclasses at issue in the upcoming TPP trial with the limited data she has or even that the data she has are reliable in the first place. Instead, plaintiffs sidestep these problems and ask the Court to accept Dr. Conti's opinions based on nothing more than her say-so that those opinions are reliable, even where the assumptions baked into her opinions are contradicted by common sense, basic economic principles and the creators of the very data she uses to calculate damages. For all of these reasons, discussed further below, her opinions should be excluded.

ARGUMENT

I. PLAINTIFFS ARE INCORRECT THAT DR. CONTI'S OPINIONS FIT THE FACTS OF THE UPCOMING TRIAL.

As explained in defendants' motion, although the subclasses in the upcoming trial are defined by the state where each TPP "paid any amount of money for" the VCDs at issue, Dr. Conti has admitted that the data she relies on only reflect the "pharmacy state," ***not*** the state in which a TPP made the relevant payment. (Dep. of Rena Conti ("Conti 2/1/24 Dep.") 67:3-13, Feb. 1, 2024 (Mem. Ex. 1); *see also id.*

68:14-69:2.) And because TPPs typically pay for medication via a PBM—which may be located in the TPP's home state, pharmacy state or some other state—the state where the pharmacy is located will often not be the state in which a TPP "paid any amount of money" for the at-issue drugs, creating a fundamental mismatch between Dr. Conti's model and what plaintiffs must prove at trial. *See Ctr. City Periodontists, P.C. v. Dentsply Int'l, Inc.*, 321 F.R.D. 193, 204 (E.D. Pa. 2017) (excluding "model [that] does not distinguish between damages attributable to the specific breach alleged in this case or 'something else'").

While the Court in its order denying defendants' motion for decertification claimed that Dr. Conti could create "a translating mechanism . . . relying on IQVIA data" that "could convert where [Point of Sale] damages were paid into those TPP [Point of Purchase] locations" using a "computer subroutine" (ECF 2657 at 6-7), neither plaintiffs nor Dr. Conti have proposed any such mechanism, and defendants are aware of none. In fact, it is likely impossible that Dr. Conti could ever create or execute such a mechanism because, by Dr. Conti's admission, neither she nor anyone else has access to the transaction-level data IQVIA uses and, as a result, she has no ability to match transactions from the point of purchase in the TPP data to specific payments at the point of sale. (*See* Conti 2/1/24 Dep. 81:7-82:11 (Dr. Conti confirming that "[n]o one," herself included, has "access to IQVIA Xponent data before it is aggregated"—i.e., the "transaction level data").)

In short, plaintiffs have not proposed any way that Dr. Conti is able to properly calculate damages for the subclasses at issue in the upcoming trial; nor does that appear possible with the data to which Dr. Conti has access. For this reason alone, her opinions are inadmissible and should be excluded from trial.

II. DR. CONTI'S WORTHLESSNESS OPINION IS UNRELIABLE.

Even if Dr. Conti could properly calculate damages for the trial subclasses, her testimony would still be inadmissible because her opinion that the at-issue VCDs were worthless is inherently speculative and unreliable. That lack of reliability is borne out by Dr. Conti's new deposition testimony, and none of plaintiffs' arguments supports a different conclusion.

First, plaintiffs' continued reliance on the *BCBS* decision is unavailing since Judge Sánchez, there, much like the Court at class certification here, did not have the benefit of Dr. Conti's concessions about how she calculates a product's value—the fundamental underpinning of her "worthlessness" opinion—from her recent deposition. (*See* Opp'n at 22-24.) As explained in defendants' opening brief, Dr. Conti testified in her recent deposition that a product's "economic value" is its "market price." (*See* Mem. at 18-20.) This highlights the absurdity of her position. Dr. Conti has never analyzed what the market price of valsartan would have been with the impurities, and neither she nor plaintiffs has provided a ***single piece*** of economic literature supporting Dr. Conti's views that adulterated (but still

efficacious) drugs have no "legitimate" market price and are therefore worthless. Instead, plaintiffs continue to rely entirely on Dr. Conti's say-so of how economics supposedly works. (*See* Opp'n at 10 & n.1 (plaintiffs claiming "no 'literature' is necessary" to support Dr. Conti's views since it is "actually health economics 101") (citation omitted).) But "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Regardless of what the *BCBS* court found about Dr. Conti's opinions and what this Court decided at class certification, Dr. Conti's worthlessness opinion is facially illogical and entirely unsupported except by her own say-so, and it should be excluded. *See Johnson Elec. N. Am. Inc. v. Mabuchi Motor Am. Corp.*, 103 F. Supp. 2d 268, 286 (S.D.N.Y. 2000).

Second, the other authority plaintiffs cite that supposedly "sides with" admitting Dr. Conti's unsupported and illogical opinions is inapposite. (Opp'n at 23.) Neither *Yachera* nor *Debernardis* had anything to do with whether an expert economist like Dr. Conti applies a reliable methodology by assuming that an efficacious drug with trace impurities has zero value; nor was either court even presented with expert opinions at all. Rather, both cases merely analyzed, at the motion-to-dismiss stage, whether a plaintiff could establish "injury in fact" as a matter of standing when alleging that they purchased medication that worked as

intended and did not cause any adverse effects. *Yachera v. Westminster Pharms., LLC*, 477 F. Supp. 3d 1251, 1263 (M.D. Fla. 2020); *see also Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1088 (11th Cir. 2019) ("Because the plaintiffs were deprived of the entire benefit of their bargain, we conclude they adequately alleged that they experienced economic loss."). Needless to say, this litigation is less than two weeks from trial, and whether such allegations suffice as a matter of standing to create a cognizable ***legal*** claim at the motion-to-dismiss stage has no bearing on whether Dr. Conti has applied a reliable ***economic*** methodology such that her opinions should be admissible at trial.

Third, plaintiffs misrepresent defendants' experts' and corporate witnesses' testimony in claiming that those witnesses "concede" that "the potential 'therapeutic value' of adulterated or misbranded VCDs is inconsequential to an economic damages analysis if the appropriate measure of damages is the benefit of the bargain," and that "adulterated drugs . . . are economically worthless." (Opp'n at 11, 29.)

For example, plaintiffs did not ask Mr. Kosty if he thought therapeutic value was relevant to a drug's value; instead, they asked Mr. Kosty to "***assume*** that even if a contaminated drug that works to lower blood pressure and, therefore, creates a clinical value . . . that drug is still worthless," to which Mr. Kosty agreed that if one assumes "those hypotheticals and with those requirements"—i.e., assumes that the

clinical value of a drug is immaterial to a drug's overall value—then the proper measure of damages is the full price of the drug. (Dep. of Timothy E. Kosty ("Kosty Dep.") 144:16-145:3, Feb. 24, 2022 (emphasis added) (Opp'n Ex. F).) Asking Mr. Kosty to accept an assumption in a hypothetical question is hardly the same thing as Mr. Kosty agreeing that the assumption is correct. Similarly, neither of ZHP's "corporate representatives" testified that "adulterated drugs . . . are economically worthless" (Opp'n at 11), only that ZHP stopped selling valsartan after it learned of the impurities (*see* Dep. of Eric Gu, Ph.D. 391:12-392:3, Apr. 6, 2021 (Opp'n Ex. H); Dep. of Min Li, Ph.D. 699:24-700:15, Apr. 22, 2021 (Opp'n Ex. K)). That plaintiffs have to resort to twisting witness testimony, but are apparently unable to address ***any*** of the authority defendants cite illustrating the commonsense notion that an efficacious drug is not worthless (*see* Mem. at 16-17 & n.7), speaks for itself.

In short, plaintiffs do not meaningfully respond to any of defendants' arguments highlighting the unreliable nature of Dr. Conti's worthlessness opinion, and her opinions should all be excluded on this ground as well.

III. DR. CONTI'S CALCULATIONS ARE UNRELIABLE.

Plaintiffs also miss the mark in their attempts to defend Dr. Conti's unreliable calculations, which are based on data that are not reliable for the purposes used by Dr. Conti. Each of these failings renders Dr. Conti's calculations unreliable and inadmissible.

First, none of plaintiffs' arguments about Dr. Conti's failure to consider offsets under Medicare Part D (*see* Opp'n at 32-35) addresses the fundamental problem with her method. As the Third Circuit has explained, "[i]gnoring 'the real world'" can "render[][an expert] opinion inadmissible." *Elcock v. Kmart Corp.*, 233 F.3d 734, 756 (3d Cir. 2000); *see also Edison Wetlands Ass'n v. Akzo Nobel Chems., Inc.*, No. 08-419 (FSH), 2009 WL 5206280, at *6 (D.N.J. Dec. 22, 2009) (an "expert's assumptions . . . cannot ignore the 'real world'"). Rather than address that authority, plaintiffs rehash their arguments from their motion to exclude Wayne Gibson's opinions, contending that evidence of offsets is barred by the collateral source rule and alternatively, that defendants "have utterly failed" to demonstrate the extent of such payments. (Opp'n at 32-34.) Those arguments miss the point. As defendants have explained in their opposition to that motion, the collateral source rule does not apply under the circumstances of this case or under the laws of several states at issue in the upcoming class trial (*see* ECF 2659 at 25-30), and defendants have demonstrated in great detail the existence of those offsets and the extent to which they apply to Dr. Conti's calculations (*see* ECF 2659 at 18-21). The fact that Dr. Conti "[i]gnor[es] 'the real world'" by refusing to consider how Medicare reimbursed the TPPs in light of that evidence is what renders her opinions unreliable and "inadmissible," regardless of who will have the ultimate burden at trial. *Elcock*, 233 F.3d at 756.

Moreover, it is of no moment that Dr. Conti "testified at length" about why she ignored the fact that several TPPs were reimbursed for purchases of at-issue VCDs through Medicare Part D since those reasons still result in a damages calculation wholly untethered to reality. (Opp'n at 33.) For example, while Dr. Conti asserts that "[she] [does]n't really view those subsidies" as ones that apply because "they are subsidizing Medicare beneficiaries[']' access to insurance and making sure that Medicare beneficiaries can afford . . . to actually be covered" (Dep. of Rena Conti ("Conti Class Rep. Dep.") 122:6-11, Feb. 10, 2022 (Mem. Ex. 6)), the fact that she does not like to "view" the subsidies that way does not change the fact that those subsidies, like the Low-Income Cost-Sharing Subsidies, represent a plan being "***reimbursed*** . . . by the federal government" for a plan's payment of an at-issue VCD (*id.* 130:11-131:3 (emphasis added)). Similarly, whether "[Dr. Conti] think[s] of" Medicare Part D payments "as being collateral payments" (*id.* 142:23-24) does not alter the entire point of CMS's bid system, under which, by Dr. Conti's own admission, "CMS help[s] to bridge the difference" "[i]f a third party payor ends up spending more" than they estimate they will spend (*id.* 126:21-127:4).

In short, regardless of who will have the ultimate burden of proving any offsets at trial, and regardless of how Dr. Conti "thinks" Medicare Part D subsidies should be viewed, Dr. Conti's failure to account for them renders her calculations unreliable and due for exclusion.

Second, plaintiffs misunderstand defendants' arguments regarding the unreliability of IQVIA Xponent data. (*See* Opp'n at 35-39.) The problem is not that using the "different inputs" of IQVIA Xponent data and real-world transaction data from pharmacies leads to different damages calculations (*id.* at 35) or that "one data set is 'better' than the other" (*id.* at 37); the problem is that IQVIA Xponent data is an unreliable data source for the purposes Dr. Conti is trying to use it. Nothing makes that more clear than IQVIA's own disclaimers—which plaintiffs do not address except to summarily dismiss them as irrelevant "boilerplate" (*id.* at 38)—specifically informing users like Dr. Conti that "a notable portion of pharmacies report list price . . . ***rather than the amount collected***," thus resulting in ***inaccurate pricing data***, and that the data are "not intended to be used as direct evidence or to establish any fact" in a legal proceeding (Mem. at 26 (emphasis added) (citations omitted)). Boilerplate or not, the creators of the very dataset Dr. Conti used have ***affirmatively disclaimed*** the reliability of the data for the very purposes Dr. Conti seeks to use them. That IQVIA Xponent data cannot form a reliable basis for Dr. Conti's calculations could not be more apparent.

Nor are plaintiffs correct that "as the Pharmacy Defendant Data comes closer to IQVIA in terms of reported quantities . . . the average prices begin to more closely approximate each other (further reinforcing the validity of the IQVIA Xponent data)." (Opp'n at 36.) Plaintiffs produced a graph supposedly illustrating that

relationship on February 14, 2024 (weeks after Dr. Conti's deposition and days after defendants had filed their motion to exclude Dr. Conti's opinions). (*See* Ex. 1 to Cert. of Jessica Davidson.) However, even a cursory review of that graph belies such a relationship. For example, as the number of pharmacy pills as a percentage of total IQVIA pills for Teva products increases from 14.3% to 56.6%, the average prices in the pharmacy claims data—which represents real-world transactions—actually ***diverges further*** from the IQVIA Xponent data. (*See id.*) Further, the data for Torrent and ZHP's medications is seemingly random, with some pills that are more represented in the IQVIA data diverging further from the IQVIA average price than pills that are less represented. (*See id.*) In short, Dr. Conti's *ipse dixit* assertion about the average prices converging in the IQVIA and pharmacy claims data is refuted by the untimely "evidence" plaintiffs have produced in an attempt to bolster their expert's opinions.

Plaintiffs are also incorrect in asserting that defendants' "own witnesses and experts" have espoused the reliability of IQVIA Xponent data. (Opp'n at 38 (footnotes omitted).) For example, Hai Wang testified that IQVIA is a "benchmark" not for pricing, but rather for "sales information" and "marketing data." (Dep. of Hai Wang 48:3-49:9, Mar. 10, 2021 (Opp'n Ex. D); Dep. of Hai Wang 499:14-502:15, Mar. 11, 2021 (Opp'n Ex. C).) While Dr. Lauren Stiroh did testify that she has worked with IQVIA's data in the past, she also specifically cautioned that the

reliability of IQVIA data depends on "what it is that [she is] using it for," and that the data "are supplemented by information on sales and prices from the manufacturers." (Dep. of Lauren J. Stiroh, Ph.D. 81:6-83:5, Mar. 25, 2022 (Opp'n Ex. E).) And when Mr. Kosty was asked by plaintiffs' counsel whether IQVIA data is the "gold standard," he merely responded that IQVIA is the "leading provider" of data to perform specific tasks like "track the performance of [a] drug product in [a] sales territory." (Kosty Dep. 134:1-15.) Plaintiffs tellingly omit Mr. Kosty's testimony that "the purpose of IQVIA data is to provide trend information to market participants," as well as his criticisms of Dr. Conti's use of the IQVIA data. (*Id.* 133:13-134:8, 161:8-162:14, 331:15-25.)

Nor does the authority plaintiffs cite support the use of IQVIA Xponent data the way Dr. Conti does here. For example, in *In re National Prescription Opiate Litigation*, an expert considered whether manufacturers of prescription opioid medications could have analyzed IQVIA data to "discover[] suspicious prescribing activity" from physicians, not to determine an average pill price to calculate damages. No. 1:17-md-2804, 2019 WL 3934470, at *5 (N.D. Ohio Aug. 20, 2019). And plaintiffs' reliance on cases involving some "IMS Health data" that they claim is "now known as IQVIA data" (*see* Opp'n at 38 n.8) does nothing to establish the reliability of IQVIA's ***Xponent*** data, since, as Dr. Conti herself explained, "Xponent data is ***one of*** the data sets that IQVIA sells, ***among many***" (Conti Class Rep. Dep.

163:20-164:3 (emphases added).) At best, those cases might support the reliability of those specific datasets for other purposes. *See, e.g., In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2008 WL 2696916, at *91 (E.D.N.Y. July 2, 2008) (noting that "two different data sources" from IMS Health were "the National Prescription Audit ('NPA') and the National Disease and Therapeutic Index ('NDTI')") (cited in Opp'n at 38 n.8).

Third, plaintiffs do not even address that Dr. Conti's use of IQVIA data violates her own stated methodology. As defendants pointed out in their motion, Dr. Conti purported to exclude claims paid by several entities to satisfy the "Valsartan TPP Class Definitions and Exclusions." (*See* Mem. at 30; *see also* Expert Decl. of Rena Conti, Ph.D. ¶ 75, Nov. 10, 2021 (Mem. Ex. 2).) However, approximately 12% of the prescription drug costs in Dr. Conti's class-wide damages calculations fall within the "UNKNOWN" or "UNSPEC" categories in the IQVIA data, which represent prescriptions that cannot be linked to a payor, PBM or plan. (*See* Mem. at 31.) Because there is no way for Dr. Conti to fully exclude payments of non-class members using the IQVIA data, something she recognized she has to do under her own methodology, her use of IQVIA Xponent data does not reflect a reliable application of her own methodology. *See* Fed. R. Evid. 702(d) (an expert's opinion must "reflect[] a reliable application of the principles and methods to the facts of the case").

CONCLUSION

For the foregoing reasons and those set forth in Defendants' opening brief, the Court should exclude the opinions of plaintiffs' damages expert, Rena Conti, from the upcoming TPP Trial.

Dated: March 6, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 6, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
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